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CHAPTER



SUMMARY AND GENERAL DISCUSSION

BACKGROUND

Even with problem-based curricula, final-year medical students are insufficiently prepared for prescribing in clinical practice [1]. The literature on medical and pharmacotherapy education point to context learning, engagement, and early clinical experience as being potentially important to further improvements in problem-based (pharmacotherapy) education [2-5]. Taking these factors together, the optimal setting for such education would be for students to prescribe and to solve actual pharmacotherapy problems involving real patients. This hypothetical setting closely resembles that of Student-Run Clinics (SRCs). SRCs are outpatient clinics completely run and organized by undergraduate (para) medical students. In these clinics, students work in the setting of their future profession (=context+), contribute to real patient care (=engagement+), and participate from their first year onwards (=early clinical experience +). Although these clinics were originally founded solely to provide (free) care to the uninsured, they may provide a perfect setting for (medical/pharmacotherapy) education [6]. Although pharmacotherapy education needs such innovative learning methods, research is needed to evaluate if and how this concept can be used. Therefore, the central aim of the studies of this thesis was to determine if and how we can assess, adjust, and use the SRC concept to improve pharmacotherapy education. This general aim led to the following research questions:

1. The concept

- I. What is known about the outcome of student participation in SRCs?
- II. How can the current SRC format be redesigned into a new, learner-centred SRC (LC-SRC) for insured patients, with a primary focus on medical education and the teaching of pharmacotherapeutics, and is this approach feasible?

2. The learning experience

- I. What type of motivation do students have to participate in an LC-SRC, and does LC-SRC participation influence students' motivation and proficiency in CanMEDS competencies?
- II. Can undergraduate medical students make a valuable contribution to the care of insured patients, and how can this care be evaluated?
- III. How does SRC participation contribute to learning, and which factors influence learning in an SRC?

3. Applying the concept to pharmacovigilance

- I. Are medical students sufficiently prepared for their role in pharmacovigilance, and what are the intention/attitudes and skills/knowledge of these students towards pharmacovigilance and reporting adverse drug reactions (ADRs)?
- II. Is the LC-SRC pharmacovigilance programme feasible and what is the educational value of such a programme in terms of students' pharmacovigilance skills and knowledge?
- III. What is the value of an ADR reporting assignment to pharmacovigilance centres and specialist nurses, are these nurses sufficiently prepared for their role in pharmacovigilance, and what are their intention/attitudes and skills/knowledge towards pharmacovigilance and ADR reporting?

In this chapter, we summarize and then discuss the findings of the previous chapters, placing them in a broader context with regard to the literature and clinical practice. Based on our findings, we provide recommendations for improving current pharmacotherapy education and future studies.

PART 1: THE CONCEPT

In order to evaluate the suitability of the SRC concept for pharmacotherapy education, we studied what is already known about the outcomes of students who participate in an SRC and how the concept could be adjusted to a European setting with insured patients.

In the study reported in **Chapter 2**, we systematically studied the literature on the outcome of student participation in SRCs, using the four levels of learning outcomes as described in Kirkpatrick's hierarchy, namely, 1-attitudes and motivation; 2-skills and knowledge; 3-behaviour; and 4- patient/health care. A total of 42 articles met the inclusion criteria and were included in the quantitative synthesis. All but 2 articles reported on students' attitudes and opinions and general healthcare outcomes of SRC participation. We found the SRC concept to be a promising setting for clinical (pharmacotherapy) education. Students like to participate, patients are satisfied with the quality of care provided, and the quality of care seems adequate. Outcomes for skills and knowledge are promising, but are predominantly based on student evaluations and (expert) opinion. This study was the first systematic review to analyse student outcomes after SRC participation. There was an earlier review but it used a non-systematic approach, and more studies have been published since [7]. In our systematic literature review, we tried to objectively measure study quality using the MERSQI instrument [8]. Overall, the quality of studies was low and a number of gaps in knowledge in this research field were identified. However, we have to realize that this instrument is biased, being focused only on measurable outcomes. In the social sciences, this bias is referred to as positivism. A pitfall of this approach is that it does not contribute to theory building by understanding how and why something works [9, 10].

Despite the promising findings regarding student enthusiasm and an adequate quality of care described in chapter 2, questions remain about whether SRCs can be used for medical (pharmacotherapy) education in a European setting. Since the number of uninsured patients is much lower in European countries than in the USA [11, 12], recruiting enough patients for an uninsured patient clinic could be a problem. For this reason, further studies with a focus on adjusting the SRC concept to fit a European setting, with insured patients and a focus on medical (pharmacotherapy) education, were needed.

In the studies reported in **Chapters 3 and 4**, we evaluated and described how the SRC concept could be adjusted to a European setting with insured patients, with a focus on medical education. We evaluated the feasibility of this first European Learner-Centred SRC (LC-SRC) with insured patients. We considered the LC-SRC feasible if the quality of care was guaranteed, patients were

satisfied, clinical supervisors and students considered the LC-SRC feasible, and sufficient attention was paid to pharmacotherapeutics. Feasibility was assessed using a set of questionnaires for all stakeholders (students, clinical supervisors, and patients). In total, 31 consultations were conducted by 31 individual students and supervised by 4 clinical specialists. In 33% of these consultations, a pharmacotherapeutic treatment plan was drawn up. The patients were content with the care provided and the supervisors considered the LC-SRC to be safe for patients and agreed that the quality of care was guaranteed. The clinicians found the LC-SRC a valuable tool in medical education, but found it time-consuming. Students appreciated their (new) responsibility for patient care and considered the LC-SRC a very valuable extracurricular activity.

The most important finding of this feasibility study was that patients were satisfied with the care provided. Although these results are comparable with those of earlier studies (chapter 2) [13-17], it is notable that even insured patients who had the possibility to choose their healthcare provider were willing to attend student consultations and were satisfied afterwards. This finding is contrary to the current defensive /risk avoiding patient safety perspective, which is omnipresent in the USA and gaining ground in Europe [18]. According to this perspective, the most experienced doctor is best for each individual patient. However, if this paradigm is applied in general, the less experienced healthcare worker (in all phases of their training) would get fewer (or even no) opportunities and responsibilities. This will have profound long-term consequences, as future doctors would then have fewer learning opportunities and less clinical experience. The SRC concept seems to contradict the safety paradigm. However, we believe that working as a team, with students and clinical supervisors together, does not compromise healthcare safety and quality but will actually improve it now and in the future.

Conclusions and recommendations

It seems attractive to train students as medical professionals by giving them responsibility for patient care early in the curriculum. Within an LC-SRC or SRC, responsibility for real patients is essential. The adjusted LC-SRC concept is feasible, and all participants considered it to be a valuable educational activity. It offers students the opportunity to learn to prescribe in clinical practice, in a real interprofessional and longitudinal setting. However, little is known about the long-term effect of SRC participation on students' skills and knowledge. Furthermore, exposure to pharmacotherapy and drug safety issues needs to be optimized in the LC-SRC. Therefore, future studies need to investigate how students learn within a SRC and how this learning can be influenced. Moreover, the benefits and learner effects of SRC participation need to be investigated in larger studies with a longer follow-up to prove durability.

PART 2: THE LEARNING EXPERIENCE

In order to study the transition from concept to practice, we evaluated the preliminary outcomes of medical students and patients who participated in an SRC and investigated factors that influence student learning in this setting.

In the study described in **Chapter 5**, we aimed to evaluate the preliminary effect of participation in an SRC on students' motivation to participate and their proficiency in CanMEDS competencies. We measured motivation with the Academic Motivation Scale (AMS) and Intrinsic Motivation Inventory (IMI), and CanMEDS competencies were evaluated by faculty, using a mini-clinical examination and a student post-participation questionnaire. The students who participated in the LC-SRC showed high levels of intrinsic motivation and perceived an improvement in their competence. Furthermore, based on their CanMEDS competencies, the clinical competence of the students was judged by their supervisors to be at junior doctor level. The LC-SRC offers a stimulating environment according to self-determination theory, and the observed high levels of intrinsic motivation and the qualitative comments of the students in this study suggest that the LC-SRC is a very attractive learning environment.

Although intrinsic motivation has been used earlier in studies of sports and dental education, this is the first study that explicitly measured intrinsic motivation in medical education and specifically in SRC projects [19, 20]. We found the intrinsic motivation of the student participants to be as high as that measured in dental students who completed a practical course in operative dentistry [19]. We expected the levels of intrinsic motivation to be high, because the characteristics of the project are known to stimulate intrinsic motivation, by stimulating autonomy (providing optimal challenges), encouraging participation, and encouraging students to accept more responsibility for their learning and patients [21]. The students' supervisors found that the students' proficiency in various competencies had improved after participation, with specific improvement in communication with patients, medical knowledge, and clinical reasoning.

These results are consistent with the students' self-evaluation – they considered that their proficiency in CanMEDS competencies had improved as a result of LC-SRC participation. These findings may be somewhat limited by social desirability and observer bias. Self-reported improvement is known to be biased and is poorly correlated with other performance measures [22], and clinical supervisors are known to overestimate performance of students [23]. Still, the results are in line with van Unen's findings, which showed that medical students (5th year) are able to perform therapeutic consultations with real patients in their clinical clerkship internal medicine [24].

In the study presented in **Chapter 6**, we evaluated whether medical students can contribute to the existing care of insured patients. In this study, a total of 46 students treated 115 individual patients in a new learner-centred student-run cardiovascular risk management programme. The patients were very satisfied with the care provided, even higher (8.43 vs 7.9) than that reported in our previous study (chapter 3). Moreover, the participating students and general practitioners were enthusiastic, considered the project enjoyable and educational, and were satisfied that this project improved the quality of care by offering a structured assessment of cardiovascular risk. These results are comparable to those of previous studies in demonstrating an adequate quality of care, and the valuable contribution of students to such programmes [15, 25–28].

This study was limited by its single centre and retrospective design and the selection bias of all participants (patients, students, and supervisors). Taken together, our findings show that undergraduate students can have an active role in real patient care with regard to cardiovascular risk management. This creates a potential 'win-win-win' situation for all participants and could offer students valuable learning opportunities with responsibility for patient care.

Despite the promising findings regarding student motivation and competence, and the adequate quality of care provided in the LC-SRC, the question remains whether the project is of additional value to medical students. It is essential to establish how SRC participation contributes to medical students' development of skills and competencies, especially if the SRC concept is to be incorporated into medical education. Therefore, we first have to understand how SRC participation contributes to learning.

In the study reported in **Chapter 7**, we explored how SRC participation contributes to learning and which factors influence this learning. Using a qualitative approach with semi-structured interviews, we gained in-depth insight into the experiences and learning of students participating in an SRC. We interviewed 20 students and analysed the transcripts using a grounded theory approach with three levels of coding. From this analysis, we distilled the framework of learning in an SRC, clarifying how SRC participation contributes to learning. The three themes that emerged, namely, responsibility, authenticity, and collaboration, are key to this framework and in combination influence learning in an SRC. To conclude, learning in an SRC is highly dependent on responsibility for a real authentic task and is stimulated by extensive collaboration with fellow students and supervising doctors. Participation in an SRC, with responsibility for the care of real patients, offers extensive learning opportunities and is highly motivating for students.

Learning in the workplace and "supported participation" are described in the experienced-based learning (ExBL) model of Dornan and Billett's general pedagogy of workplace learning [4, 29]. Our findings are consistent with their findings regarding authenticity (related to participation) and collaboration (relating to support). However, these models appear to lack emphasis on responsibility and collaboration. The ExBL model seems more passive than our model, is primarily focused on support, and does not regard self-direction and responsibility as core conditions for experience-based learning [30, 31]. A contrasting theory relating to this responsibility issue is Vygotsky's Zone of Proximal Development (ZPD). According to the ZPD, learning can be maximized by assigning students tasks that are just within their capabilities [32, 33]. The ZPD theory considers it essential to challenge students, because providing too much assistance or structure may hinder learning – students will complete the task, but they will not learn to do the task independently [32]. In our study, this balance between optimal challenge and support was reflected by students commenting that while LC-SRC participation was highly challenging on the one hand, they felt that they were supported by the coordinators and supervisors on the other.

A fourth related model is the Self-Determination Theory (SDT), which focuses on motivation. As reported in chapters 5 and 7, motivation is both a consequence and a facilitator of learning

in an SRC. According to the SDT, motivation has intrinsic and extrinsic components: the intrinsic component originates from within oneself, and extrinsic component originates from external factors [34–36]. Intrinsic motivation stimulates in-depth learning, performance, and competence [35, 37–39]. Extrinsic motivation can be transformed into the favourable intrinsic motivation by internalization [40], and is stimulated by autonomy, competence, and relatedness [41]. Comparing previous studies to our present study, we see commonalities and differences. Two commonalities are the overlap between collaboration and relatedness, and that between authenticity and autonomy. The most important difference concerns the role of responsibility. The theme responsibility is not directly described in the SDT or as a driver of internalization/intrinsic motivation. We hypothesize that responsibility stimulates internalization and intrinsic motivation because it makes a task worthwhile, creates task engagement, and supports autonomy.

Both the findings from our studies and the ZPD theory support the conclusion that there is a lack of attention for responsibility and collaboration in the current ExBL, SLT, and SDT models, and highlight the need to take these issues into account in theory development and workplace-based learning practice.

Conclusions and recommendations

Students and clinical supervisors who participated in the LC-SRC were enthusiastic about the learning opportunities and care provided. Students showed high levels of intrinsic motivation to participate in the LC-SRC and perceived an improvement in their competence that was acknowledged by the supervisors. Three themes were identified that described how SRC participation contributed to learning, namely, responsibility, authenticity, and collaboration. These findings are supported by the ExBL, SLT, ZPD and SDT theoretical frameworks, although we found responsibility to be an additional important contributor to workplace learning. Our results highlight the need to pay more attention to the theme responsibility in educational research and when designing educational interventions to optimize patient management and drug safety. An LC-SRC is a novel and stimulating teaching and learning environment. Future research is warranted to further explore the effects of responsibility in medical education and on workplace learning.

PART 3: THE CONCEPT APPLIED TO PHARMACOVIGILANCE

In order to further evaluate student-run training in real-life practice, we applied and evaluated the ‘learner-centred student-run education concept’ to pharmacovigilance. Pharmacovigilance is the monitoring of drug safety after marketing approval. We chose this specific subject to enrich students’ exposure to pharmacotherapeutic problems, such as the management of adverse drug reactions (ADRs). Pharmacovigilance depends on the adequate reporting of ADRs. In this part, we first investigated the preparedness of future prescribers for their role in pharmacovigilance. We then designed and evaluated the educational value of a student-run pharmacovigilance programme and ADR reporting assignment.

In the study reported in **Chapter 8**, we investigated the preparedness of future prescribers for their role in pharmacovigilance, using a nationwide E-survey. This survey consisted of questions about pharmacovigilance awareness, skills, and knowledge. Overall, 874 students participated, almost all of whom intended to report serious ADRs in their future practice. Unfortunately, more than half of the students did not know where to report an ADR and an even larger proportion did not know which items were necessary for a good-quality ADR report. While more than 78% of the students agreed that pharmacovigilance is an important topic in their medical education, only 26% thought that their curriculum covered pharmacovigilance adequately. Thus while ADR reporting is considered relevant and important by future doctors, many do not know where and what to report. This is highly undesirable and should have consequences for pharmacotherapy teaching. Earlier research identified multiple factors underlying the low level of ADR reporting, such as indifference, lethargy (including lack of motivation and time), and negative expectations of the result of reporting [42]. Contrary to these findings, we found the medical students in our study to have favourable intentions and attitudes to ADR reporting, and had better scores for this than pharmacists and pharmacy students in earlier studies [43, 44]. Thus the willingness to report ADRs is not the problem, but instead the lack of knowledge of how to do so. A solution to this problem is to encourage active involvement and to gain practical experience (chapter 8). This finding seems to be consistent with the findings of a study among trainee general practitioners, in which a practice-based method led to more and better documented ADR reports than a lecture-based approach [45]. Exposure and practice are known to be necessary to master clinical skills – ‘practice makes perfect’ [46].

In the study presented in **Chapter 9**, we evaluated the educational value of a student-run pharmacovigilance programme by analysing student assessments and evaluating student attitudes, intentions, skills, and knowledge of ADR reporting, by means of E-questionnaires before and after programme participation. In total, 43 students assessed 100 different ADR reports. We found that undergraduate medical students made useful, scientifically substantiated, accurate, and complete assessments of ADR reports. Moreover, the participating students were positive about ADR reporting, their awareness of ADR reporting increased, and they would probably report ADRs in the future. Therefore, the student-run pharmacovigilance programme has mutual benefits for students and pharmacovigilance.

As there is limited evidence regarding effective educational interventions to improve pharmacovigilance in undergraduate medical students [47], we could not compare our findings with those of previous studies. However, the results were comparable with those of other studies presented in this thesis, which found that undergraduate medical students could make a valuable contribution to patient care (chapters 3, 4, 5, 6, 7). The outcomes investigated in this study were used in previous studies that evaluated the attitudes and intentions of (future) healthcare professionals. Compared with these studies, the students who participated in our programme had a more positive attitude towards reporting serious and unknown ADRs and had higher intention scores than pharmacists, and pharmacy and medical students [43, 44, 48].

Still, these data must be interpreted with caution because the follow-up time was limited and participants enrolled on a voluntary basis.

In the study reported in **Chapter 10**, we developed and evaluated the quality, relevance, and educational value of a novel real-life ADR reporting assignment for nurses. Thirty-three ADRs were reported, 32 of which were well documented according to the clinical documentation tool to assess individual case safety reports. Two-third of the reports were especially relevant – they were either ‘serious’ according to CIOMS-criteria; listed for additional monitoring by the European Medicine Agency (EMA); or not mentioned in the Summary of Product Characteristics. In an E-questionnaire, all nurses agreed that the reporting assignment was useful, that it fitted in daily practice, and that it increased their attention for medication/patient safety. A large majority of 85% agreed that the assignment had changed how they would deal with ADRs in the future. Our results show that specialist oncology nurses have positive attitudes/intentions and adequate skills/knowledge to report ADRs. Moreover, the reporting assignment is a useful training tool that yielded valuable, relevant, and well-documented ADR reports for oncology and pharmacovigilance practice.

This was the first study to design and evaluate an ADR reporting assignment for nurses, which makes it difficult to compare our findings with other findings. The completeness of the ADR reports filed by nurses in an earlier study was only 48% (95%CI 42.4-53.7) [49], and healthcare professionals scored a mean of 78% on the ClinDoc instruments’ pilot study [50], whereas in our study the mean ClinDoc score was higher, 89%. Most of the reported ADRs were highly relevant for pharmacovigilance, because the ADR was serious or the suspect drug was listed by the EMA for additional monitoring. In 39% of the reports, the ADR was serious according to CIOMS criteria, a significantly higher percentage than that reported in three earlier studies of ADR reporting by nurses [49, 51, 52]. Moreover, our findings are consistent with those of other research presented in this thesis regarding the positive effect of giving learners a legitimate role in the pharmacotherapy problems of real patients (chapters 3, 4, 5, 6, 7 and 9). This finding, while preliminary, suggests that a practical assignment is a useful and valuable tool both for learning and patient care/pharmacovigilance practice. Although the follow-up time was short and the number of participants small, we believe practical assignments in which learners are responsible for real pharmacotherapy problems are highly educational.

Conclusions and recommendations

While future doctors consider ADR reporting relevant and important, many do not know where and what to report. This is highly undesirable and should have consequences for pharmacotherapy teaching. Although limited evidence exists regarding effective educational interventions to promote pharmacovigilance among future healthcare professionals, students benefit and appreciate active involvement and practical experiences. We designed and evaluated two innovative interventions. The student-run pharmacovigilance programme and the ADR reporting assignment were designed to enable students to have responsibility for real pharmacotherapy problems. As their first

impression of ADR reporting and pharmacovigilance was positive, their willingness to reporting increased, and they would be more likely report ADRs in the future. Therefore, the student-run pharmacovigilance programme and the ADR reporting assignment were beneficial to both students and pharmacovigilance practice.

Although very positive and valuable, these results should be interpreted with caution because of the limited follow-up time and small sample size. Therefore, future research is needed to investigate the long-term effects of these interventions and education in pharmacovigilance and drug safety.

Measuring outcomes of SRC participation

Throughout this thesis, we assessed outcomes of SRC participation, either in general in our systematic literature review or more specifically in the LC-SRC of the VU University Medical Centre. When we started the LS-SRC project, we hoped we could prove the additional value of SRC participation, using objective and quantitative outcomes. The need for “hard outcomes” has been acknowledged previously [53-55]. Hard outcomes encompass outcomes related to the highest levels in Miller’s pyramid and Kirkpatrick’s model [56, 57]. There are a number of challenges to hard outcomes research in medical education, namely, 1: dilution (progressively attenuated impact of education resulting from contributions from other healthcare providers and systems), 2: inadequate sample size, 3: failure to establish a causal link, 4: potentially biased outcome selection, and 5: teaching to the test [10]. When applied to SRC outcome research, this encompasses the following limitations:

1. The dilution of effect in the SRC raises the question whether the good patient care outcomes are really the result of the contribution of the student, or the result of increased collaboration with and supervision of the patient.
2. Inadequate sample size can be a major limitation, especially if, for instance, the calculated power is higher than the number of actual participants. The number of participants and consultations depends on the number of patients, and for this reason the number of participants in SRCs is often limited.
3. Establishing a causal link encompasses dealing with the internal validity (the absence of bias in the study findings) and external validity (the meaningfulness of the findings to others) of the study. In the present SRC, selection bias is an important threat to validity and generalizability. Students often select themselves, as participation is predominantly an extracurricular activity. It is therefore uncertain whether the studied outcomes of participation are generalizable to mandatory education within the curriculum.
4. Outcome selection is very difficult, because there are no reliable predictors of future competence. In practice, researchers select measures that are the easiest rather than the best. When comparing an intervention group with a control group, another potential problem is a miss-match in alignment. For instance, differences in the intervention level versus the testing level in Miller’s pyramid [57]. For example, involving students in real patient care as intervention (“does”), a high-level activity, and testing their knowledge etc (“knows” / “knows how” / “shows”) at a lower level.

5. Teaching to the test means that coordinators and supervisors might pay extra attention to the outcomes studied, paying less attention to other important (but not tested) subjects. This phenomenon is also known as “squeezing the balloon” [58].

In designing the studies presented in this thesis, we faced most of these challenges, the hardest of which was outcome selection. The outcomes we studied in this thesis are depicted in figure 1, for which we used the four levels of Miller’s pyramid, which are “knows”, “knows how”, “shows how” and “does” [57].

Reviewing these outcomes and the outcome measures used, we covered most levels, except for the level “shows how”. This is not surprising given our explicit focus on learning based on real legitimate participation in the pharmacotherapeutic care of real patients. The level “shows how” encompasses a simulation setting to assess clinical competence. The original pyramid of Miller is two dimensional and based on outcome hierarchy [57]. However, this model does not take study quality and risk of bias into account. Another important observation is that some of the studies and outcomes used cannot be placed in this pyramid, such as intrinsic motivation and qualitative outcomes. These outcomes are not quantitative, thus “softer” but still of the greatest importance for understanding how students learn in SRC and how this learning is influenced. These outcomes do not provide evidence for “superior efficacy of learning in SRCs”, but do contribute to our knowledge and understanding of workplace-based learning.

Strengths and Limitations

This is the first evaluation of a European SRC focused on learning while providing care for insured patients. Therefore, most studies were pragmatic in design, an approach with inherent strengths and limitations. The main strength is the practical approach in a real-life setting (not simulated or only designed on paper) together with the use of quantitative, qualitative, and mixed-methods study designs. These studies evaluated a novel approach to workplace-based learning in pharmacotherapy and pharmacovigilance.

The limitations of the research presented in this thesis include the single setting (in all studies, except those described in chapters 2 and 8), namely, the VU University Medical Centre, although different departments and department-sections participated and facilitated the LC-SRC. Furthermore, the studies reported in this thesis had no control (or “placebo”) group, which made comparison with “usual care” impossible. Moreover, the follow-up time in all studies was limited, resulting in unknown long(er) term outcomes of participation. The outcome measures of the various studies varied, as elaborated on in the Discussion “Measuring outcomes of SRC participation”.

Final conclusions and recommendations

The LC-SRC is a very stimulating environment, given the importance of early clinical experience, workplace-based learning, and self-determination theory. This thesis shows the LC-SRC to be a feasible concept that results in satisfied patients, students, and supervisors. Moreover, the

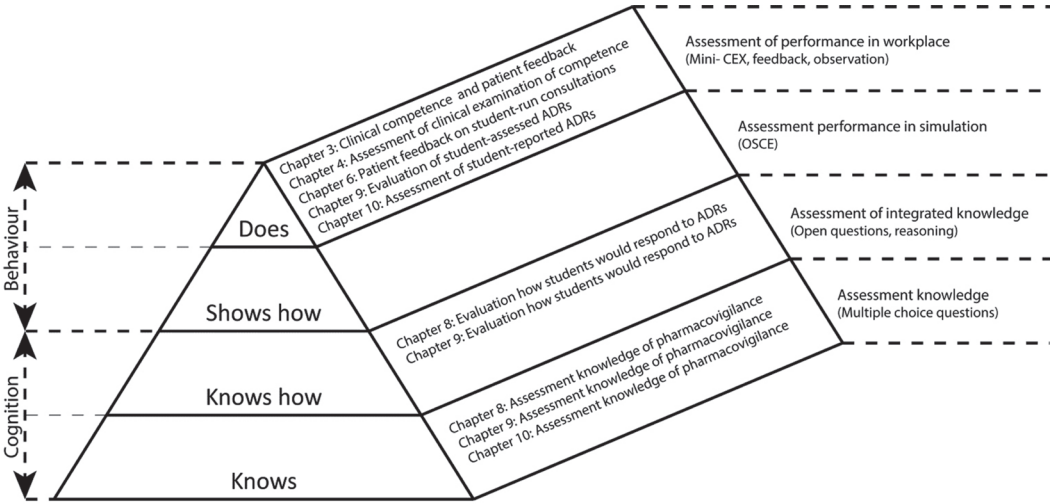


Figure 1: The outcomes used in the studies in this thesis, organized according to Miller’s pyramid of learning outcomes. Within the “knows how” and “knows” levels, these outcomes were assessed/evaluated in different (student) populations. Mini-CEX: Mini-Clinical Evaluation Exercise; OSCE: Objective Structured Clinical Examination; [57].

concept is generalizable to other settings (in different outpatient clinics, a GP practice, and in collaboration with a national pharmacovigilance centre). The factors underlying learning in the SRC are responsibility, authenticity, and collaboration. Although this thesis focused on the concept of SRCs, the studies described in chapters 7–9 show the importance of the same concepts and factors to the development of medical/pharmacotherapy education related to pharmacovigilance.

Implications for practice

The findings of this thesis have a number of implications for future practice and provide suggestions about how to implement workplace-based (pharmacotherapy) education, contribute to the understanding why this workplace-based learning is valuable, and offer direction for future developments in medical (pharmacotherapy) education. This is necessary in order to better prepare future doctors to prescribe safely and rationally and to safeguard patient safety.

Recommendations

The findings of this thesis offer many opportunities for further research. In relation to pharmacotherapy education research in general, important topics for further research are the role and value of responsibility in (pharmacotherapy) workplace learning. It is important to identify a valid and reliable outcome measure to evaluate pharmacotherapy education, in order to provide future researchers with valid, usable outcome measures. A possible candidate outcome measure is the therapeutic script concordance test. This test assesses clinical reasoning and can be used

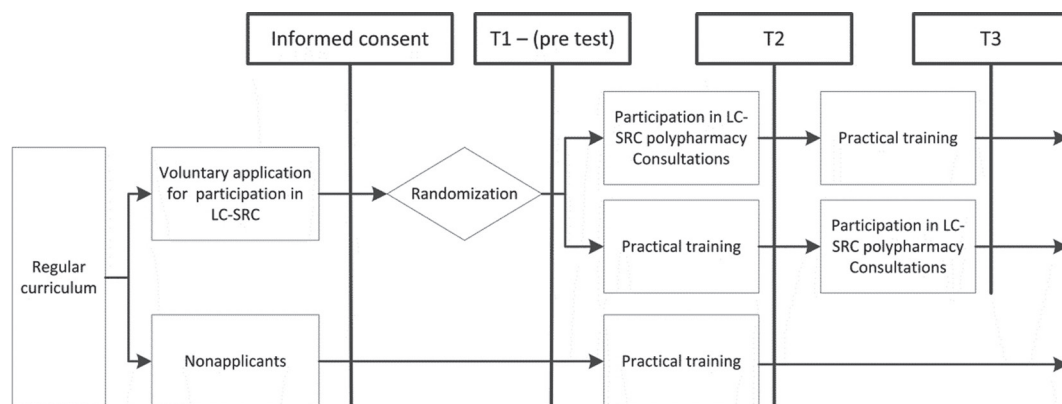


Figure 2: Example of a randomized clinical trial to evaluate the effect of participation in a learner-centred student-run clinic (LC-SRC). This example entails an evaluation of polypharmacy consultations in the LC-SRC compared to regular curricular pharmacotherapy practical classes. As outcome measure (tests, T1, T2, T3), the above-mentioned script concordance test could be used.

to evaluate individual growth in clinical reasoning skills and differentiate between test subjects of varying levels of competence [59–62]. Both these characteristics are important criteria for usability as outcome measure.

Based on principles from clinical pharmacology and drug research, it would be interesting to perform a randomized clinical trial to evaluate the effect of participation in an SRC. However, blinding, outcome selection, and selection of the “standard of care/placebo” would be challenging. A possible scheme for such study is displayed in figure 2.

Other important topics for further research into SRCs are the (long-term) effects of participation on students’ skills and knowledge and its effect on their future practice. Such long-term follow-up studies should preferably also include the patients seen in SRCs, to enable evaluation of the care provided. In the specific case of clinics that offer care to non-underserved populations, it would also be interesting to explore why insured patients are willing to participate in these projects. Moreover, the possible additional value of interprofessional collaboration within SRCs is of interest, because interprofessional education is gaining more attention in current medical education research and practice [63].

When other SRC projects are started, research is needed to further determine the generalizability of the LC-SRC concept to different settings, both within the Netherlands and other European countries. The most important recommendation, however, would be to involve participating students in research into the value of these clinics, so as to offer students not only a learning experience with regard to patient care, but also with regard to scientific practice.

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